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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,936	11/14/2003	Deborah A. Schade	19400/09143	9680
27530	7590	12/27/2006	EXAMINER	
NELSON MULLINS RILEY & SCARBOROUGH, LLP 1320 MAIN STREET, 17TH FLOOR COLUMBIA, SC 29201			WANG, SHENGJUN	
			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE		DELIVERY MODE	
3 MONTHS	12/27/2006		PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/713,936	SCHADE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Shengjun Wang	1617	

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-40 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-40 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

## DETAILED ACTION

This application is a divisional application of 09/381,484.

### *Double Patenting Rejections*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, and 21 of copending Application No. 09/381,484. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims herein are generic to the claims in '484. Note, the "infants" herein read on both term and preterm infant. As to the source of ARA and DHA recited in the claims, it is noted that the source of a compound is not seen to carrier any patentable weight. A compound is the same regardless how to make it.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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3. Claims 1-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, and 19-20 of copending Application No. 10/714,268. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims herein are generic to the claims in '484. Note, the "infants" herein read on both termed and preterm infant. As to the source of ARA and DHA recited in the claims, it is noted that the source of a compound is not seen to carrier any patentable weight. A compound is the same regardless how to make it.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections 35 U.S.C. 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle (U.S. Patent 5,374,657, IDS) in view of Schweikhhardt et al (EP 0231904, IDS).

Kyle teaches an infant formula comprising DHA and ARA in comparable amounts of DHA and ARA in human breast milk. The ratio of ARA:DHA is about 3:1 to 2:1. See the claims and the examples in columns 13-16. Kyle also teaches that the presence of ARA and DHA in infant food is critical for a healthy growth for infants. See, particularly, column 1, lines 29-53.

Kyle does do teach expressly the particular ratio of ARA: DHA, and the particular amounts of ARA: DHA herein, or the particular infant formula with the amounts of protein, lipid, and carbohydrate.

However, Schweikhardt et al. teach to employ ARA and DHA enriched infant formula for feeding infant, including preterm infant, wherein the ration of ARA and DHA is essentially the same as herein claimed. Schweikhardt et al. teach that newborn baby, particularly the preterm baby, is dependent on exogenous supply of ARA and DHA. See, particularly, page 1, the third paragraph and the claims of the English translation. Schweikhardt et al. further teach an oil mixture for infant formula comprising 0.12 –1% of ARA and 0.05 –0.5% of DHA. Schweikhardt et al. teach an infant formula comprising 1.5% protein, 3.6% lipid, and 7.2% of carbohydrate. These amount would translated to about 5-42 mg/kcal of ARA and 2.1 to 21 mg/kcal of DHA in a infant formula (based on 100 ml of infant formula contain 3.6 g of oil mixture and 120 ml of infant formula provide 100 kcal of energy (see table 1 at pages 5-6 of the translation).

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a infant formula with the particular amount of ARA and DHA herein and use the same for feeding infant.

A person of ordinary skill in the art would have been motivated to make a infant formula with the particular amount of ARA and DHA herein and use the same for feeding infant, because infants are known to be in need of food with sufficient amount of ARA and DHA and the particular amounts of ARA and DHA herein are overlapped with the amounts range known in the art. Further, optimization of a result effective parameter, such as he amount of ARA, and DHA in infant formula, is considered within the skill of the artisan. See, In re Boesch and Slaney

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(CCPA) 204 USPQ 215. The optimization of the amounts of ARA and DHA, or the formula as whole, by using more ARA and DHA than those in breast milk, particularly for preterm infants are considered within the skill of artisan since the criticality of ARA and DHA for preterm infant growth is known in the art. Note the claimed ratio of ARA:DHA is within the broad range claimed by Kyle. See, particularly, claim 20 in Kyle.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
SHENGJUN WANG  
PRIMARY EXAMINER  
Shengjun Wang  
Primary Examiner  
Art Unit 1617